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Application Serial No. 09/930,330
Attorney Docket No. PC10942A
Amendment "A" (37 CFR § 1.111)

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By

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: **CHAHWALA, ET AL.**

APPLICATION NO.: **09/930,330** : Examiner: **Kevin E. Weddington**

FILING DATE: **AUGUST 15, 2001** : Group Art Unit: **1614**

TITLE: **THERAPEUTIC COMPOSITIONS COMPRISING
EXCESS ENANTIOMER**

Commissioner for Patents
Washington, D.C. 20231

Sir:

APPLICANTS' AMENDMENT 37 C.F.R. § 1.111

Responsive to the Office Action mailed November 20, 2002, reconsideration of the Examiner's rejection of all of the presently pending claims is respectfully requested in view of the following remarks.

Claims 1-20, 29, and 33 are presently pending in the above-identified application. Said claims have been rejected by the Examiner under 35 U.S.C. 103(a) as being unpatentable over Chahwala et al. in view of Foster and further in view of Budavari et al. for the reasons of record as set forth in the Office Action mailed June 16, 2002, on pages 3 and 4 thereof. The Examiner's rejection is traversed for the reasons set forth below.

Responding to the Applicant's contention that Chahwala and Foster teach away from the invention of the present claims, because they each disclose and suggest only the S(-) and R(+) enantiomers, respectfully, the Examiner now takes the position that Applicant's contention is not persuasive "since the Applicants are merely claiming the racemate of amlodipine." The Examiner has further commented that "the Applicants are merely combining the R(+) and S(-) of amlodipine together to form a racemic mixture of amlodipine."

Applicants would point out to the Examiner that claim 1 and all of the claims dependent thereon or referencing its content, contain the following limitation:

"... wherein the enantiomers are present in a ratio by weight
(based on free base) of R(+) enantiomer: S(-) enantiomer of
greater than 1:1."

Grant & Hackh's Chemical Dictionary, Fifth Edition, McGraw Hill, Inc., 1987, defines "racemic" as having the following meaning:

"Indicating that equal amounts of enantiomeric molecules are
present together, irrespective of whether in crystalline, liquid, or
gaseous form."

From the above it is clear, Applicants submit, that they are not "merely claiming the racemate of amlodipine", since the present claims are clearly limited in scope to pharmaceutical compositions and methods for their preparation and use, wherein the ratio by weight (based on free base) of R(+) enantiomer: S(-) enantiomer is greater than 1:1. A racemic mixture, which by definition must comprise a ratio of 1:1 of the enantiomers, inherently falls outside the scope of the present claims.


The teachings of Chahwala and Foster fail, accordingly, to make out a case of prima facie obviousness for the reasons of record in Applicants' Amendment mailed September 9, 2002. The teachings of Budavari et al. additionally cited by the Examiner does nothing to make up for the shortcoming in the Examiner's case. To the contrary, Budavari et al. actually supports the Applicants' contentions herein.

For example, Campbell et al. U.S. Patent No. 4,572,909 cited in Budavari et al. at Column 1, line 60 to Column 2, line 2, discloses that amlodipine may exist as a pair of enantiomers which may be separable by physical methods, and that the invention includes the separated pair as well as mixtures thereof, "as racemic mixtures or as separated d- and l-optically-active isomeric forms." There is no disclosure or suggestion whatever of a mixture of the enantiomer of amlodipine which is other than racemic, i.e., 1:1.

The Examiner is urged to withdraw the rejections of the present claims and to allow this case to issue, for the reasons expressed in detail further above.

Respectfully submitted,

Date: 20 March 2003



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